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08/789,270

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/789,270	01/28/97	WALDMAN	S TJU-2115

18M1/0429

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ART UNIT 1 PAPER NUMBER 4
1806
DATE MAILED: 04/29/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 1/28/97

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 9-19 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 9-19 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____, is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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Part III DETAILED ACTION

Claims 1-8 have been canceled and claims 9-19 have been entered by the amendment filed January 28, 1997. Claims 9-19 are pending in the application.

Copies of the PTO form 1449s filed in patent application serial no. 08/305,056 are requested to complete the record in the instant application.

Double Patenting

Claims 9-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,601,990. Although the conflicting claims are not identical, they are not patentably distinct from each other. Instant claims 9-13 are directed to methods of determining whether an individual has metastasized colorectal cancer by detecting ST receptor protein or mRNA that encodes ST receptor protein in a sample of extraintestinal tissue and/or body fluid; instant claims 14-19 are directed to kits containing the reagents used in the methods. Patented claims 1-8 are directed to methods of determining whether an individual has metastasized colorectal cancer **cells** by detecting ST receptor protein or mRNA that encodes ST receptor protein in a sample of extraintestinal tissue and/or body fluid,

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and also to methods of determining whether a cell is of colorectal origin by detecting ST receptor on its surface. One of ordinary skill in the art would have recognized that the instant methods and the patented methods are essentially the same: an individual with metastasized colorectal cancer necessarily has metastasized colorectal cancer cells. Moreover, the instant kits would have been obvious over either of the instant or patented methods because it would have been obvious for one of ordinary skill in the art to have assembled the reagents used in the methods in kit form for the recognized advantages of improved assay standardization and convenience.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 19 is rejected under 35 U.S.C. § 103 as being unpatentable over Garbers et al. (PN 5,237,051).

Garbers et al. disclose amplification of the nucleic acid encoding the ST receptor by PCR using primers that specifically amplify mRNA that encodes ST receptor protein. Garbers et al. differ from the instant invention in not disclosing kits for analysis of samples by PCR, but it would have been obvious for one of ordinary skill in the art to have assembled the reagents used by Garbers et al. in kit form for the recognized advantages of improved assay standardization and convenience; moreover, instructions are conventional in assay kits. Note that the preamble of the claim, which recites that the kit is "for determining whether an individual has metastasized colorectal cancer" is a statement of intended use which does not distinguish the kit components from components used to analyze a sample for ST receptor mRNA for some other purpose.

Claims 14-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Vaandrager et al. (J. Biol. Chem., vol. 268, no. 3, pp. 2174-2179, January 25, 1993, abstract only).

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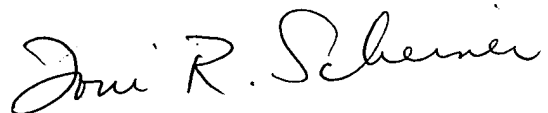
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Vaandrager *et al.* disclose immunodetection of ST receptor on cells expressing the protein using antibodies raised to the carboxy-terminal sequence of the receptor. The reference differs from the instant invention in not disclosing kits for immunoanalysis of samples for the presence of ST receptor, but it would have been obvious for one of ordinary skill in the art to have assembled the reagents used by Vaandrager *et al.* in kit form for the recognized advantages of improved assay standardization and convenience; moreover, instructions are conventional in assay kits, as are negative and positive controls. Note that the preamble of the claim, which recites that the kit is "for determining whether an individual has metastasized colorectal cancer" is a statement of intended use which does not distinguish the kit components from components used to analyze a sample for ST receptor for some other purpose.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Toni R. Scheiner whose telephone number is (703) 308-3983.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

4/28/97



TONI R. SCHEINER
PRIMARY EXAMINER
GROUP 1800